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(71) Applicant *(for all designated States except US)*: MÖLNLYCKE AB [SE/SE]; S-405 03 Göteborg (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)* : FABO, Tomas [SE/SE]; Stenåsvägen 15, S-435 41 Mölnlycke (SE).

(74) Agents: HYLTNER, Jan-Olof et al.; Noréns Patentbyrå AB, Box 27034, S-102 51 Stockholm (SE).

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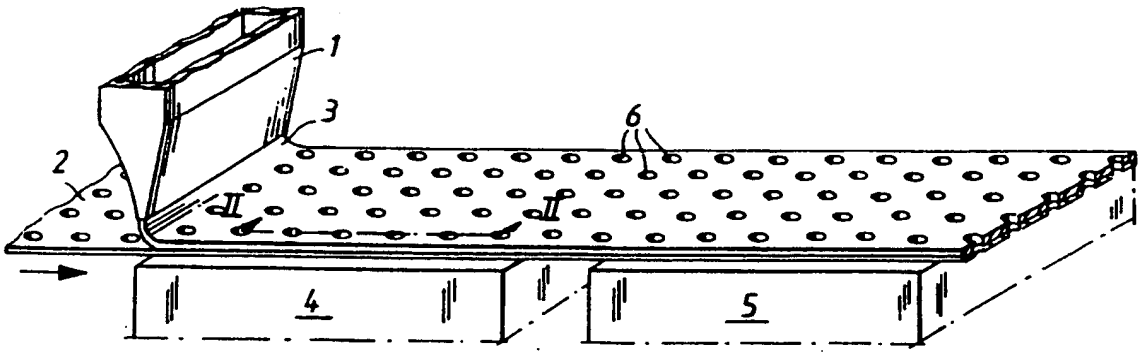

(57) Abstract

The present invention relates to a method of manufacturing a wound dressing. According to the invention, the upper surface of a perforated carrier material (2) is coated with a curable silicone mixture (3) and cold air is blown onto the underside of the coated carrier material. Heat is then applied to the silicone mixture until it has cured to a silicone gel. The invention also relates to an arrangement for carrying out the method, and also to a wound dressing manufactured in accordance with the method.

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A Method and An Arrangement for Manufacturing Wound Dressings, and a Wound Dressing Manufactured in Accordance with the Method

The present invention relates to a method and to an arrangement of apparatus for manufacturing wound dressings of the kind which comprise a perforated carrier material and a layer of hydrophobic silicone gel which lies against the wound, or sore, when the dressing is worn. The invention also relates to a wound dressing manufactured in accordance with the inventive method.

A wound dressing of this kind is known from our European Patent No. 0,261,167, in which the carrier material is fully enclosed by the silicone gel although while leaving openings through the dressing. When manufacturing a dressing of this kind, the carrier material is dipped into a mixture of those components which, when cured, form the hydrophobic silicone gel, and the carrier material is then transferred to a curing oven in which the carrier material is cured. In order to ensure that the silicone gel is uniformly distributed on both sides of the carrier material and that the perforations do not become clogged with gel, the carrier material is guided in the oven in a relatively complicated path. This known method is not suited to high production rates.

The object of the present invention is to provide a method which will enable such wound dressings to be manufactured at a high production rate and in a simple and reliable manner.

The invention also relates to apparatus for carrying out the method and to a wound dressing suitable for manufacture by means of the inventive method.

To this end, an inventive method is characterized by

applying a coating of a thermosetting silicone mixture to the upper surface of a perforated carrier material; blowing cold air onto the undersurface of the coated carrier material; and then applying heat to the silicone mixture until it has cured. The cold air blown onto the underside of the carrier material acts to blow the thick, viscous silicone mixture away from the perforations in the carrier material, so as to form through penetrating perforations and also to prevent clogging of the perforations in said carrier material. At the same time, the cold air flow ensures that the silicone mixture will not begin to cure before it has time to spread over the carrier material. The flow of air through the carrier material will, of course, also prevent the silicone mixture from running through the perforations in said material.

Apparatus for carrying out the aforedescribed method is characterized in that it includes means for coating the upper surface of the carrier material with a mixture of components which, when cured, form a silicone gel; an air-blowing unit for blowing cold air onto the underside of the carrier material, which is placed opposite the coating means, and means for delivering heat to the component mixture subsequent to having applied said mixture to the upper surface of the carrier material.

A wound dressing suited for manufacture by means of the aforesaid method is characterized in that the carrier material is comprised of a material which is impervious to air and fluid, or only slightly permeable to air and fluid; and in that the carrier material has a silicone gel coating on solely one side thereof.

The invention will now be described in more detail with reference to an exemplifying embodiment thereof and also with reference to the accompanying drawings,

in which

Figure 1 is a schematic perspective view of part of an inventive arrangement for manufacturing a wound dressing, and also illustrates an exemplifying embodiment of an inventive wound dressing manufactured by means of said arrangement;

Figure 2 is a cross-sectional view taken on the line II-II in Figure 1; and

Figure 3 is a cross-sectional view of another exemplifying embodiment of an inventive wound dressing.

Figure 1 illustrates schematically part of an arrangement for manufacturing an inventive wound or sore dressing. The arrangement includes a unit in the form of an extruder nozzle 1 for coating a perforated carrier material 2 with a thermosetting silicone mixture 3 which includes components which when cured form a chemically cross-linked, sticky silicone gel, for instance the silicone gel which is retailed by Dow Corning and specified in the aforesaid European Patent No. 0,261,167, or the silicone gel retailed by Wacker Chemie GmBH and designated Wacker RTV-2, VP7612. The carrier material 2 is moved in the direction shown by the arrow in Figure 1, by means not shown. These means may conveniently comprise a belt conveyor, a stentor means, to which the long side edges of the carrier material are attached, or some like means. Mounted beneath the movement path of the carrier material is an air-blowing unit 4, which extends from the nozzle 4 to a point located slightly downstream thereof. A further air-blowing unit 5 is also mounted beneath the movement path of the carrier material 2, downstream of the blower unit 4.

The arrangement operates in the following manner:

The perforated carrier material 2 is unrolled onto a conveyor, preferably from a storage reel, and is moved by the conveyor in under the extruder nozzle 1 by means of which the carrier material is coated with the thermosetting silicone mixture 3, which prior to curing has the consistency of a thick, viscous fluid. Cold air is blown onto the underside of the carrier material with the aid of the unit 4 and the air flows through the perforations 6 in the carrier material, as illustrated with arrows in Figure 2, and blows away the silicone mixture in the regions above the perforations, so as to provide through penetrating holes in the silicone mixture. The carrier material 2 coated with silicon mixture 3 is then moved to a position above the blower unit 5, which blows hot air onto the underside of the carrier material. The silicone mixture will then begin to cure in the regions around the perforations, where the exchange of heat is greatest. When the regions around the perforations have cured sufficiently, the supply of hot air is preferably cut-off and the carrier material coated with said silicone mixture is passed into a curing oven.

Hot air shall not be blown onto the carrier material in the initial stage of the manufacturing process, since it is necessary for the silicone mixture to spread and be properly dispersed over the carrier material before the curing process begins. It is also important that the nozzle 4 is not heated, since this will incur the risk of the nozzle becoming blocked or clogged.

In order to prevent the silicone mixture from being blown from the carrier material, it is essential that the carrier material is impervious to air, or at least so impervious that essentially all air will flow through the perforations. However, material which permits air to diffuse therethrough can be used bene-

ficially when practicing the invention. The carrier material shall also be impervious to fluid, or at least have a fluid-permeability which is so low that the thick-viscous fluid, i.e. the silicone mixture prior to curing, is unable to run therethrough.

Suitable carrier materials are relatively soft plastic sheets, such as polyethylene, polyamide, polyurethane, silicone film, etc.

The plastic sheet may also be microporous, i.e. have a sufficiently low fluid and air-permeability to satisfy the aforesaid requirements, so as to present a large surface area for adhesion between plastic sheet and silicone mixture. In order to ensure good adherence between silicone gel and plastic sheet, the plastic sheet may be coated with a silicone primer, for instance with Dow Corning 355 Medical Adhesive.

Another method of ensuring good adherence between silicone gel and carrier material is to use a perforated two-ply material as the carrier material. This two-ply material may, for instance, consist of a laminate which comprises a plastic sheet and a layer of non-woven or textile material which can be laminated with the aid of heat or a binding agent. The two-layer material may also be comprised of a coated fibre material having a plastic film moulded on one side thereof.

That side of the carrier material which is not coated with silicone gel will preferably have a uniform and smooth surface, so as to have low adherence to any dried wound fluid which may have exuded through the perforations as the dressing is worn. This is particularly important when the dressing is used together with an overlying absorbent body or pad, since it must be possible to remove the absorbent body without the dressing being disturbed as a result of wound fluid

that has dried on the absorbent body adhering to the carrier material and entraining the material in the initial stages of removing the absorbent body.

Figure 3 illustrates a further embodiment of an inventive wound dressing. This wound dressing differs from the dressing illustrated in Figures 1 and 2, insomuch that the carrier material 7 is comprised of a plastic film having perforations 8 provided in the bottoms of cup-shaped projections in the plastic film. Such plastic films are known to the art and are sometimes used as casing sheets for diapers and similar absorbent articles. In addition to the surface area for adhesion between silicone gel and the plastic sheet being greater than the surface area of the embodiment of the inventive dressing described with reference to Figures 1 and 2, the cupped shape of the projections 9 also reduces the risk of non-cured silicone mixture running down into the perforations 8 during the process of manufacture. This obviates the need, or at least greatly reduces the need, of blowing hot air onto the carrier material before passing the carrier material and its silicone coating into a curing oven.

When practicing the method of manufacture taught by EP-C 0,261,167, it is necessary to transport that part of the material to be embraced by silicone gel in an unsupported fashion. When practicing the present invention, on the other hand, the carrier material can be transported on an air-permeable conveyor, provided that the holes in the conveyor are sufficiently large to ensure that the delivery of air onto the underside of the carrier material will not be disturbed thereby. Thus, when practicing the inventive method, the carrier material can be transported at a higher speed than in the case of the aforesaid known method and the conveyor path can be guided much more easily than in the earlier known case.

In the case of the described embodiment of the inventive method of manufacture, the carrier material is comprised of a continuous web which is moved past the nozzles and the air-blowing units. Although this embodiment is to be preferred, it lies within the scope of the invention to hold the carrier material stationary and to move nozzles and air blowers in relation to said material.

As will be understood, modifications can be made to the described embodiment of the inventive arrangement for manufacturing an inventive wound dressing within the scope of the present invention. For instance, the air-blowing units 4 and 5 may be combined to form a single unit and may be supplied with air under pressure from one and the same source, for instance from the same blower fan, which may be beneficial in obtaining an homogenous air flow in the longitudinal direction. The hot air section of such a unit will include an appropriate heat source, such as electrical heating wires or filaments. Furthermore, at least the hot air-blowing unit will be conveniently accommodated in a housing which will enable the heat content of the hot air to be better utilized for delivering heat to the silicone mixture coated on the carrier material from above.

This invention thus provides a simple and effective method of manufacturing a wound dressing having a layer of hydrophobic silicone gel which is intended to lie against the wound or sore, and a layer of carrier material which when the dressing is worn faces outwardly and which is not sticky and will not adhere to clothing and the like. As in the case of the aforesaid known dressing, the layer of hydrophobic silicone gel which lies against the wound or sore is soft and adheres to dry skin, and the inventive dressing will therewith facilitate healing of the wound in the same beneficial fashion as the known dressing. According to

the present invention, the silicone gel is comprised of chemically cross-linked, two-component addition-curing silicone gel.

The carrier material will preferably have 0.5-200 perforations per cm^2 and the perforations will preferably have a diameter of 0.1-2 mm. When practicing the inventive method of manufacture, good homogeneity is obtained with regard to the size of the perforations in the gel layer, therewith enabling an inventive dressing to be constructed for smaller-sized perforations than the aforesaid known dressing, without the risk of the perforations being clogged or blocked by silicone gel in the manufacturing process.

The silicone gels used in accordance with the present invention are soft and will adhere to dry skin but not to the wound or sore. This extremely low or weak adhesion to wounds as compared with other so-called non-adhesive dressings is achieved because the silicone gel has an extremely low surface tension and a surface chemistry which forms other types of adhesion forces on the wound surface than other polymeric and metallic materials used in such dressings, wherewith the strength at which the silicone gel adheres to the wound surface is weaker than practically all of these polymers and metallic materials. The silicone gel is also form-stable, i.e. it retains its original form when handled normally. Thus, the silicone gel undergoes no plastic deformations when the dressing lies against the wound or when the dressing is removed or when protective covering strips are peeled from the gel surface, etc. The gel surface obtained when practicing the inventive method is also very smooth and even, which also contributes to the poor adhesion of the gel layer to the wound surface. The majority of other types of so-called non-adhering dressings have a larger available surface area than the inventive dressing, as seen both macroscopically and microscopi-

cally, which results in stronger adhesion to the wound and to the dried wound fluid.

The strength at which the silicone gels used with the inventive dressing adhere to dry skin is considerably lower than the adhesive strength of those adhesives used with conventional self-adhesive tapes used to secure wound dressings, or those adhesives used with conventional self-adhesive wound dressings. Thus, the skin will not be damaged or injured by the adhesive silicone gel when removing the inventive dressing. One method of measuring this adhesive strength is to stick 25 mm wide strips of an inventive dressing onto dry skin and to allow a weight attached to one end of the strip to draw the dressing gravitationally from the skin at an angle of 160° thereto. The weight which will draw, or peel, the dressing from the skin at a speed of 1 mm/s can be determined with the aid of this test. The adherency measured in accordance with this test shall lie within the range of 5-200 g, preferably within the range of 20-60 g, in order to provide satisfactory adhesion and dressing peelability.

The hardness of the silicone gel is measured by means of a method in which a round steel rod having a flat end and a diameter of 9.2 mm is pressed into the gel to a depth of 5 mm. The force required to achieve this depth of penetration is measured during the process. A silicone gel suitable for use in an inventive dressing will have a hardness which lies in the range of 0.5-10 N. An optimum hardness value is 2 N.

The penetrability of a silicone gel is measured with the aid of a method in which a conical test body is allowed to sink gravitationally into the silicone gel. The number of mm through which the test body has sunk over a time period of 5 seconds constitutes the penetration value. In this test, there is used a cone obtained from Sommer & Runge AG and designated

Petrotest Sommer & Runge 18-036.1, which is filled with glass spheres to a weight of 62.5 g. A silicone gel suitable for use in an inventive dressing will have a penetrability which lies within the range of 5-20 mm. An optimum penetrability value is 9 mm.

The tensile strength of a silicone gel is determined with the aid of a method in which a gel test strip is fastened vertically between two clamps, of which one can be moved at a constant speed. The strip is stretched to a point at which it fractures and the maximum fracturing force is recorded. A silicone gel suitable for use with an inventive dressing will have a tensile strength within the range of 1-8 N/10 mm in the case of a 3 mm thick strip, and will preferably be 4 N/10 mm.

In addition to adhering to dry skin, the silicone gel will also adhere to other dry surfaces, and a good estimate of the adherence of the gel to dry skin can be obtained by measuring the force with which the gel adheres to a highly polished steel plate. The adherence of the silicone gel to a steel surface is determined by means of a method in which a test strip of silicone gel is applied to a steel plate and the strip then drawn or peeled from the plate with the withdrawn part of the strip being held at an angle of 90° thereto. The force required to withdraw or peel the strip from the plate is recorded. A silicone gel suitable for use with an inventive dressing will have an adhesive force within the range of 0.5-10 N/50 mm, preferably 2 N/50 mm, as measured in accordance with this method.

Claims

1. A method of manufacturing wound dressings, characterized by applying a coating of curable silicone mixture (3) to the upper surface of a perforated carrier material (2); blowing cold air onto the underside of the coated carrier material; and applying heat to the silicone mixture until it has cured.

2. A method according to Claim 1, characterized by blowing hot air onto the underside of the coated carrier material (2) after blowing cold air thereonto until the silicone mixture (3) has cured.

3. A method according to Claim 2, characterized by interrupting the delivery of hot air onto the underside of said coated carrier material before the silicone mixture (3) has completely cured; and terminating the curing process in an oven.

4. A method according to any one of Claims 1-3, characterized by taking the carrier material (2) from a storage reel and passing the material past a station (1, 4) in which the upper surface of the material is coated with a silicone mixture (3) while, at the same time, delivering a flow of cold air to the underside of said material essentially perpendicularly to said underside and then passing the carrier material coated with said silicone mixture past a device (5) which functions to blow hot air onto the underside of said carrier material.

5. An arrangement for manufacturing a wound dressing which comprises a perforated carrier material (2) and a layer of hydrophobic silicone gel (3), characterized in that the arrangement includes means (1) for coating the upper surface of the carrier mate-

rial with a mixture of components which when cured form a silicone gel, an air-blowing unit (4) which functions to blow cold air onto the underside of the carrier material and which is placed opposite the coating means (1), and means (5) for delivering heat to the component mixture applied to the upper surface of the carrier material.

6. An arrangement according to Claim 5, c h a r a c t e r i z e d in that the hot-air delivery means has the form of a hot-air blowing unit (5).

7. A wound dressing comprising a perforated carrier material (2) and a layer of hydrophobic silicone gel (3) which lies against the wound surface when the dressing is worn, c h a r a c t e r i z e d in that the carrier material is impervious to air and fluid, or only slightly permeable to air and fluid; and in that the carrier material is coated with silicone gel on only one side thereof.

8. A wound dressing according to Claim 7, c h a r a c t e r i z e d in that the carrier material (2) is comprised of a relatively soft plastic film.

9. A wound dressing according to Claim 8, c h a r a c t e r i z e d in that the plastic film is microporous.

10. A wound dressing according to Claim 7, 8 or 9, c h a r a c t e r i z e d in that the carrier material (2) is coated with a silicone primer.

11. A wound dressing according to any one of Claims 7-10, c h a r a c t e r i z e d in that the carrier material is comprised of a two-ply material, including a plastic layer and a layer of fibre material.

Fig.1

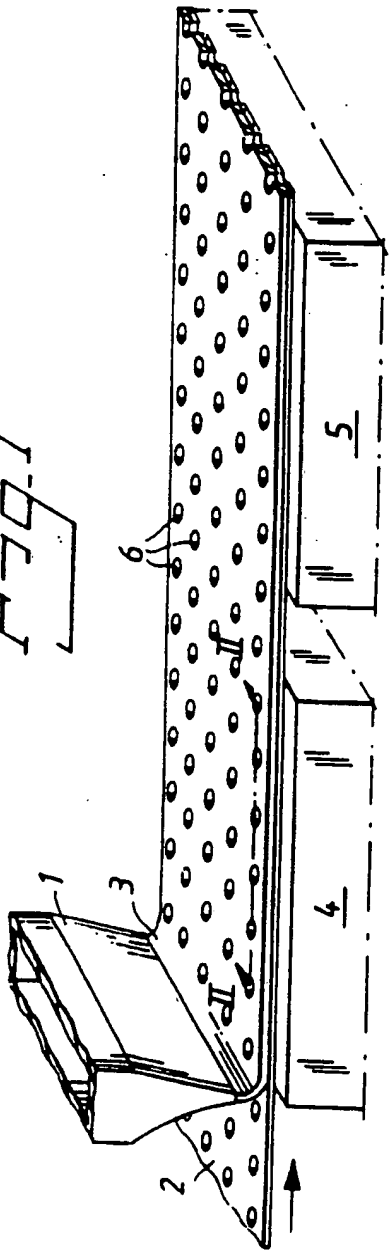

Fig.2

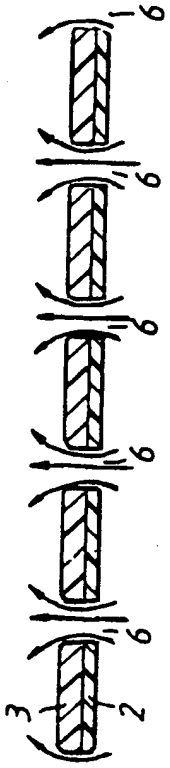

Fig.3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 93/00270

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61F 13/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A2, 0251810 (JOHNSON & JOHNSON), 7 January 1988 (07.01.88), column 5, line 28 - line 30	7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 June 1993	01 -07- 1993
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INTERNATIONAL SEARCH REPORT
Information on patent family members

30/04/93

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0251810	07/01/88	SE-T3- 0251810	
		AU-B- 604714	03/01/91
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		DE-A- 3782095	12/11/92
		GB-A,B- 2192142	06/01/88
		GB-A- 2226780	11/07/90
		US-A- 4838253	13/06/89

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